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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,046	02/28/2002	Masanobu Munekata	81833.0035	6922

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LOS ANGELES, CA 90071-2611

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/090,046

Applicant(s)

MUNEKATA ET AL.

Examiner

DR. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-12 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/486,020.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

1. Claims 8-12 are presented for examination and are examined on merits.

### **Objection To Specification**

2. 35 U.S.C. § 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. § 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., Page 5, lines 6-7, "but brought no good solution....", and line 17, "from extracted a tooth of mammalia"; Page 11, Line 9 and Page 17, Line 23, "removed not remaining using a scaler..". The examiner suggests that the applicant should carefully revise the specification including the abstract to make the specification clearly comprehensible. The applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### **Objections to Claims**

3. At the end of Claim 12, the second period (i.e. ".") should be deleted.

### **Double Patenting**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

5. Claims 8, 10 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2b and 3 of U.S. Patent No. 6,429,193. Although, conflicting claims are to a process and a composition and

therefore, not exactly identical, claims 1, 2B and 3 of referenced patent are drawn to a composition comprising the same ingredients to obtain a pharmaceutical composition as claimed in the cited claims of instant application.

### ***Claim Rejections - 35 U.S.C. § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. §112:

***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

7. Claims 8-9 and 12 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

From the record of the present written disclosure applicant has demonstrated the preparation and properties (e.g., molecular weight of 67kd, isoelectric point of 6.5 and the amino acid composition) of a "purified gingival fibroblast chemotactic factor (CCTF)" from bovine tooth cementum or precementum, because the preparation and/or properties of said CCTF from the cementum or precementum from any other mammal tooth has not been exemplified. Thus, the specification, while being enabling for CCTF from the cementum or precementum obtained from a bovine tooth, does not reasonably provide enablement for preparation of the CCTF from any mammalian tooth with these properties. Therefore, the specification, as disclosed does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112

***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

9. Claims 8-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation, "consisting essentially of a factor with a molecular weight" at Line 3, renders Claim 8 unclear and therefore indefinite since this claim as presented does

not clarify whether the molecular weight referred to is that of CCTF, or of another factor which is a component of CCTF. Appropriate correction is requested.

- The recitation, "precementum- and/or cementum-derived" at Line 2 of claim 12 is unclear as well as confusing, and therefore, indefinite because the word "derived" does not clearly define as to how similar a material should be to the base material to be called a derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Examiner suggests that the applicants delete the phrase, "precementum- and/ or cementum derived" at Line 2 of Claim 12 and insert the phrase--obtained from precementum and/or cementum--after the word "(CCTF)".

All other cited claims depend directly or indirectly from Claim 8 and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 U.S.C. § 102***

10. The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

***A person shall be entitled to a patent unless -***

***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

11. Claims 8-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ogata et al. (Comp. Biochem. Physiol., Vol. 116B (3): 359-365, 1997)

The claims recite a "purified gingival fibroblast chemotactic factor (CCTF)" obtained from the cementum and/ or precementum of a bovine tooth. The CCTF is soluble in saline and has a molecular weight of 67,000  $\pm$ 1000 as measured by SDS-PAGE. The said fibroblast chemotactic factor is a glycoprotein with an isoelectric point of 6.5 $\pm$ 0.5 and its amino acid composition has been presented in Claim 9. The said factor is a component of a drug composition to accelerate the adhesion of new connective tissue.

Ogata et al. disclose a purified (page 360, Column 1, Paragraphs 2-3 and Column 2, paragraphs 1-2) proteinaceous chemotactic factor (abstract, line 8, page 359) that is saline soluble and is obtained from enamel, dentin, cementum, and bone of a bovine tooth (page 360, column 1 lines 20-26). Ogata et al., also disclose that the proteinaceous chemotactic

factor purified from "G" extract of cementum is a protein with a molecular weight of 67 kd and has an isoelectric point of ~6.5 (Figure 2A, Page 361) and shows highest chemotactic activity toward human gingival fibroblasts (HGF, Page 363, Figure 5, Panel A). The Ogata et al., reference, however, does not describe the amino acid composition of the said proteinaceous chemotactic factor purified from "G Extract" of bovine tooth cementum, nor does it indicate whether this protein is glycosylated. However, the amino acid composition and glycosylation are an inherent property of <sup>the</sup> protein. Please note that Ogata et al., disclose a purified proteinaceous chemotactic factor that is obtained from the same source (i.e., bovine tooth cementum) as is recited in the claimed invention. Furthermore, the purified proteinaceous chemotactic factor that Ogata et al., have obtained from the bovine tooth has similar characteristics (i.e., molecular weight of ~67kd and isoelectric point of ~6.5) and has the same functionality (i.e., accelerated chemotactic activity of human gingival fibroblasts) as is recited in the claimed invention. Therefore, the prior art composition appears to be inherently identical to the claimed composition (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

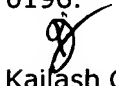
## CONCLUSION

12. No Claims are allowed.

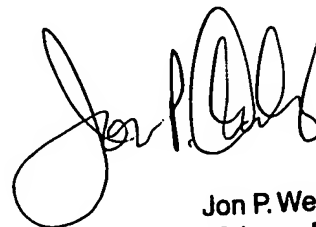
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P. M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. Mr. Wityshyn can normally be reached on Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
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November 14, 2002



Jon P. Weber, Ph.D.  
Primary Examiner